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10/730,347	12/05/2003	Richard C. Fuisz	1199-21	1795

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EXAMINER	
VAKILI, ZOHREH	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,347	FUISZ ET AL.	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *2-12 and 20-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13-19 and 30-33* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/2004 and 8/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are presented for examination.

Applicant's response to the restriction requirement filed on May 14, 2007 is acknowledged. Accordingly, Applicants elect Group I the composition. Applicants election of the species for the film-forming matrix is polydextrose, menthol crystals as the decongestant agent, and eucalyptus oil as the oil. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 1-5, 7-11, and 16 are currently amended. Claims 2-12, 21-29 are withdrawn from consideration as being directed to non-elected subject matter. Claims 1, 13-20 and 30-33 read on the elected invention and are herein examined on the merits.

Applicant's Information Disclosure Statements (IDS) filed 4/12/2004 and 8/12/2004, have been received and entered into the application.

Claim Objections

Claim 20 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim as it multiply depends from claims 1, 18, or 19 and claim 19 is multiply dependent on claims 1 and 18. See MPEP § 608.01(n). Accordingly, the claim 20 not been further treated on the merits.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claim is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 1 12, first paragraph with respect to the claimed invention." (MPEP 2173).

The term "essentially free" is a relative term, which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Because the term "essentially free" would invite subjective interpretations of whether or not a particular ingredient amount is included by or excluded from the present claims, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims

fail to meet either the tenor or express requirements of 35 U.S.C. j 1 12, second paragraph and are properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 13-19, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (US Patent No. 6596298 B2), in view Eisenstadt et al. (US Patent No. 5846557), along with Oppenheimer et al. (US Patent No. 4980169), taken with Damani et al. and further in view of Babich et al. (US Patent No. 6395299 B1).

Leung et al. teach physiologically acceptable films, including edible films, are disclosed. The films include a water soluble film-forming polymer such as pullulan. Edible films are disclosed that include pullulan and antimicrobially effective amounts of the essential oils thymol, methyl salicylate, eucalyptol and menthol. The edible films are effective at killing the plaque-producing germs that cause dental plaque, gingivitis and bad breath. The film can also contain pharmaceutically active agents. Methods for producing the films are also disclosed (see abstract). In a second embodiment of the invention, the rapidly dissolvable film acts as a vehicle for administering a pharmaceutically active agent orally, through a mucous membrane or an open wound of a patient (see col. 3, lines 8-11). The invention is also directed to a method for producing a supple, non-self-adhering film especially suitable for oral delivery. The method comprises mixing a film forming agent and at least one stabilizing agent to provide a film-forming mixture; dissolving water-soluble ingredients in water to provide an aqueous solution; combining the film-forming mixture and the aqueous solution to provide a hydrated polymer gel; mixing oils to form an oil mixture; adding the oil mixture to the hydrated polymer gel and mixing to provide a uniform emulsified gel; casting the uniform gel on a substrate; and drying the cast gel to provide a film (see col. 3, lines 12-22). The film-forming agent used in the films according to the present invention can be selected from the group consisting of pullulan, **hydroxypropylmethyl cellulose**, **hydroxyethyl cellulose**, **hydroxypropyl cellulose**, **polyvinyl pyrrolidone**, **carboxymethyl cellulose**, **polyvinyl alcohol**, sodium alginate, polyethylene glycol, **xanthan gum**, tragacanth gum, guar gum, **acacia gum**, **arabic**

gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl polymer, amylose, high amylose starch, hydroxypropylated high amylose starch, **dextrin**, pectin, **chitin**, **chitosan**, levan, elsinan, collagen, **gelatin**, **zein**, gluten, soy protein isolate, **whey protein** isolate, casein and mixtures thereof. A preferred film former is pullulan, in amounts ranging from about 0.01 to about 99 wt %, preferably about 30 to about 80 wt %, more preferably from about 45 to about 70 wt % of the film and even more preferably from about 60 to about 65 wt % of the film (col. 4, lines 64-67 & col. 5, lines 1-13). Suitable sweeteners that can be included are those well known in the art, including both natural and artificial sweeteners. Suitable sweeteners include, e.g.: A. water-soluble sweetening agents such as monosaccharides, disaccharides and polysaccharides such as xylose, ribose, glucose (dextrose), mannose, galactose, **fructose** (levulose), sucrose (sugar), maltose, invert sugar (a mixture of fructose and glucose derived from sucrose), partially hydrolyzed starch, corn syrup solids (see col. 6, lines 25-32).

Eisenstadt et al. teach the present invention pertains to chewing gum compositions containing cough suppressing agents. The compositions include a taste-masking mixture containing a flavoring agent, an intense sweetening agent and menthol. This combination nullifies the taste or off-note of the cough suppressant. The present invention also pertains to a method preparing the chewing gum composition and methods of treatment which include administering the cough suppressant-containing chewing gum to a patient in need thereof (see abstract). The present invention is directed to medicament-containing chewing gum compositions. In

particular, the present invention is directed to chewing gum compositions which effectively mask the unpleasant tastes of the medicaments contained therein over extended chewing periods (see col.1, lines 7-12). People suffering from throat irritation or experiencing coughing commonly take throat lozenges, cough syrups or cough drops for symptomatic relief (see col.1, lines 13-15). The chewing gum compositions can also include one or more additional medicaments which act in a therapeutically complementary fashion with the antitussive compound. For example, the chewing gums can include one or more of the following compositions selected from a wide variety of drugs and their acid addition salts. Both organic and inorganic salts may be used provided the drug maintains its medicament value. A non-limiting list of illustrative categories and specific examples includes: antihistamines and **decongestants** (see col. 5, lines 1-11). The flavoring agents (flavors, flavorings) of the present invention include those flavors known to the skilled artisan. These flavoring agents include natural, artificial and synthetic flavor oils and flavoring aromatic and/or oils, oleoresins and extracts derived from plants, leaves, flowers, fruits, and so forth, and combinations thereof. Non-limiting representative flavor oils include spearmint oil, peppermint oil, **eucalyptus oil**, oil of nutmeg, allspice, mace, oil of bitter almonds, menthol and the like (see col. 6, lines 29-37). The flavoring agent may be absorbed onto water soluble materials, such as cellulose, starch, sugar, maltodextrin, gum arabic and so forth or may be encapsulated (see col. 6, lines 55-58). The flavoring agent of the present invention may be used in many distinct physical forms well known in the art to provide an initial burst of flavor and/or a prolonged sensation of flavor. Physical

forms include free forms, such as spray dried, powdered, and beaded forms, and encapsulated forms, and mixtures thereof (see col. 6, lines 59-65). The gum composition may include effective amounts of conventional additives selected from the group consisting of sweetening agents (sweeteners), plasticizers, softeners, emulsifiers, waxes, fillers, bulking agents, mineral adjuvants, flavoring agents (flavors, flavorings), coloring agents (colorants, colorings), antioxidants, acidulants, thickeners, mixtures thereof and the like. Some of these additives may serve more than one purpose. For example, in sugarless gum compositions, the sweetener, e.g., sorbitol or other sugar alcohol or mixtures thereof, may also function as a bulking agent. Similarly, in sugar containing gum compositions, the sugar sweetener can also function as a bulking agent. The plasticizers, softeners, mineral adjuvants, colorants, waxes and antioxidants discussed above as being suitable for use in the gum base may also be used in the gum composition. Examples of other conventional additives which may be used include emulsifiers, such as lecithin and glyceryl monostearate, thickeners, used alone or in combination with other softeners, such as methylcellulose, alginates, **carrageenan**, **xanthan gum**, **gelatin** carob, tragacanth, locust bean, and c**arboxylmethyl cellulose**, acidulants such as malic acid, adipic acid, citric acid, tartaric acid, fumaric acid, and mixtures thereof, and fillers, such as those discussed above under the category of mineral adjuvants. The fillers when used may be utilized in an amount from greater than about 0% to about 60%, by weight of the gum composition. Bulking agents (carriers, extenders) suitable for use include sweetening

agents selected from the group consisting of monosaccharides, disaccharides, polysaccharides, sugar alcohols, and mixtures thereof; **polydextrose** maltodextrins; minerals, such as calcium carbonate, talc, titanium dioxide, dicalcium phosphate, and the like. Bulking agents may be used in amounts up to about 90%; by weight of the final gum composition, with amounts from about 40% to about 70%, by weight of the gum composition being preferred, with from about 50% to about 65%, by weight, being more preferred and from about 55% to about 60%, by weight of the chewing gum composition, being most preferred (see col. 9, lines 21-59).

Oppenheimer et al. teach the present invention relates to improved formulations for confections which are intended to reside in the oral cavity for a period of time while being consumed. In particular, the present invention provides, among other things, medicinal tablets with enhanced flavored delivery as the confection dissolves in the oral cavity (see col. 1, lines 6-11). Confections, especially medicinal tablets which deliver active ingredients in the oral cavity, are well known in the art and may be divided into various classes based upon their composition or intended effect. Examples include lozenges, compressed tablets and other medicinal tablets. The confections may have breath fresheners, breath deodorants, cough suppressants, nasal **decongestants** and the like (see col. 1, lines 12-19). Enhancing the impact of the volatile oils in the oral cavity increases the benefit of the confection by ameliorating perceived bitterness, pungency, or other undesirable organoleptic sensations (col. 1, lines 33-36). Menthol is isolated principally from the oil of Mentha arvensis. In its commercial form, **menthol is present as crystals** obtained from a process

involving cooling of the above mentioned oil. Fractional distillation of peppermint oil which usually contains from about **50% to about 65%** menthol provides another important source of menthol. In addition, menthol can be provided synthetically (see col.1, lines 37-44). The use of menthol, for example, for its medicinal effect is known in the art. Menthol's cooling effect to the mouth is useful to relieve local irritations in the throat and mouth (see col.1, lines 45-48). Eucalyptus is another essential oil often combined with other **essential oils** such as menthol in confection formulations to impart medicinal effect. In particular, **eucalyptus** is believed to exhibit an expectorant action. The combination of the essential oils of menthol and eucalyptus, in a formulation capable of dissolving in the oral cavity provide a useful medicinal preparation in treatment of coughs and minor mouth, throat, and upper respiratory irritations (see col. 1, lines 49-57). Confections which include such medicinal formulations are cough drops, lozenges, etc. (see col. 1, lines 58-59). In a preferred embodiment, the confection contains both menthol and eucalyptus as the volatile oil component. In this embodiment, the confection confers medicinal benefits by providing active ingredients which relieve irritations of the nasopharyngeal region caused by coughing as well as providing a decongestant effect in the nasal cavity by vapor action released from the confection (see col. 4, lines 14-23). L-menthol and eucalyptus oil may be combined to provide the volatile oil component of the confection. When so combined, the menthol-eucalyptus is useful as an adjunct to coughing cold therapy (col. 8, lines 12-15). There are no teachings of surfactant, plasticizer, and

polyalcohol in this composition. Therefore, Oppenheimer et al. teach a composition for decongestant free of surfactant, plasticizer, and polyalcohol.

Damani et al. teach pharmaceuticals for oral ingestion can take many different forms, such as liquids, emulsions, suspensions, aerosol sprays, solid capsules or tablets. Many pharmaceutical compositions including **oral decongestants** contain unpalatable ingredients and are therefore marketed in the form of liquids and sprays. Pharmaceutical compositions in the form of **tablets or capsules which are intended to be swallowed** whole are also widely marketed. Taste-masking of the active ingredients contained in such products can be effected by covering the tablet with a thin and quickly dissolving coating, for example, using a gelatin outer shell in order to retain the active ingredient until the tablet has been swallowed. Alternatively, the tablet can be compressed sufficiently so that it stays intact for the short time that it is in the mouth (col. 1, lines 15-29). Suitable flavouring agents include an aromatic flavouring agent selected from menthol, peppermint oil, camphor, eucalyptol, **eucalyptus oil**, preferably Menthol (see col. 4, lines 15-17).

Babich et al. teach the prodrugs and/or matrices may, if desired, be presented in a pack or dispenser device which may contain one or more unit dosage forms containing the active ingredient. The pack may for example comprise **metal** or plastic **foil**, such as a blister pack. The pack or dispenser device may be accompanied by instructions for administration (see col. 59, lines 14-19).

Clearly, one having ordinary skill in the art would have been motivated to use the teachings of Leung et al. for the preparation of a rapidly dissolvable film which acts as a

vehicle for administering a pharmaceutically active agent orally. Eisenstadt et al. teach flavorants and the bulking agent such as polydextrose in decongestants along with the teachings of Babich et al. for the packaging and enclosure of the product. As combined, the teachings of Leung et al. for making an orally consumable films taken with the teachings teachings of Oppenheimer et al. for using volatile oil such as eucalyptus oil and flavor enhancing in cough drops, the bulking agent for the decongestant is taught by Eisenstadt et al. and the packaging of the product taught by Babich et al., result in the claimed invention.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the teachings of the above references and produce a film delivery system for volatile decongestants.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner
1614

June 13, 2007

25 JUN 07

6/25/07

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